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(54) Improvements in or relating to a method of dispensing and/or a dispenser.

(57) A dispenser and a method of using the dispenser which comprises a supply means (1) for supplying inhalable material in inhalable form, the supply means (1) being in connection with atmosphere and a mouth piece (3). Flow controls means (8) are provided which allow or substantially prevent the flow between the supply means (1) and the mouth piece (3) and supply means (1) and the atmosphere. A signalling means (24) which indicates to the user when to inhale and detection means (14) to detect the commencement of inspiration and/or expiration and to cause the flow control means to cause or allow the inhalable material to move from the supply means (1) to the mouth piece (3) during a selected part of the period of inspiration.

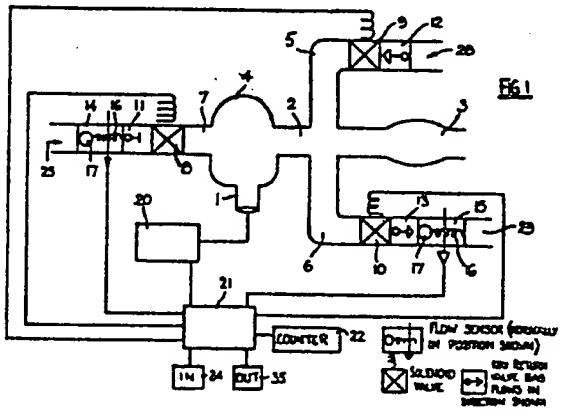

Fig 1

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IMPROVEMENTS IN, OR RELATING TO, A METHOD OF DISPENSING AND/OR A DISPENSER

This invention relates to a method of dispensing and/or a dispenser.

Current dispensers of, in particular, inhalable material in aerosol form, require the aerosol generating mechanism (such as a nebulizer) to operate in an inefficient mode and this results in different sized doses as the size of the dose depends upon how the generating mechanism is used. This is wasteful of the drug and the variability in dose size can result in under or over dosing.

It is therefore an object of the present invention to provide a method of dispensing and/or a dispenser which will obviate or minimise the foregoing disadvantages in a simple yet effective manner, or which will at least provide the public with a useful choice.

Accordingly, in one aspect the invention consists in a method of dispensing inhalable material comprising the steps of indicating to a patient that a breath should be taken, detecting the state of breathing, and causing or allowing said inhalable material to be supplied to the mouth or nose of the patient during a selected part of the period of inspiration.

In a further aspect, the invention consists in a dispenser comprising a supply means to supply inhalable material in inhalable form, said supply means being in connection with atmosphere and a mouth

or nose piece, flow control means to allow or substantially prevent flow between said supply means and said mouth or nose piece and said supply means and said atmospnere, signalling means to indicate to the user when to inhale, detection means to detect the commencement of inspiration and/or expiration and to cause said flow control means to cause or allow said inhalable material to move from said supply means to said mouth or nose piece during a selected part of the period of inspiration.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applicatons of the invention will suggest themselves without departing from the scope of the invention as defined in the appended Claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

One preferred form of the invention will now be described with reference to the accompanying drawings in which:

Fig.1 is a diagrammatic layout of a dispenser according to one preferred form of the invention;

Fig.2 is a simplified circuit block diagram of a control unit with the dispenser of Fig.1;

Fig.3 is a layout as for Fig.1 of an alternative form of the invention;

Fig.4 is a circuit block diagram of a control unit as for Fig.2 for the dispenser of Fig.3.

Referring to the drawings, a dispenser and/or a method of dispensing are provided as follows. The dispenser of Fig.1 comprises a supply means to supply inhalable material in inhalable form. This may be, in particular, any known type of aerosol generator or aerosol propellant such as a nebulizer 1. The aerosol may be processed by baffles to remove particles above a selected size and particles removed may be fed back into the nebulizer 1.

Referring to Figs. 1 and 2, a conduit 2 is provided from the nebulizer 1 to a mouth or nose piece 3 and the conduit 2 may lead from a cloud chamber or aerosol reservoir 4. Thus, particles produced by the nebulizer 1 may pass through the reservoir 4 along the conduit 2 to the mouth piece 3. A pair of branch conduits 5 and 6 may lead from the conduit 2, the conduit 5 allowing air to be inhaled and the conduit 6 allowing air to be exhaled. A conduit 7 extends from the chamber 4. Flow control means are provided in each conduit and thus, a valve 8 is provided in conduit 7, a valve 9 in conduit 5 and a valve 10 in conduit 6. Associated with each valve 8, 9 and 10 is a non-return valve 11, 12 and 13 directed to allow air flow in only the desired direction. The valves 8, 9 and 10 are desirably electrically operated comprising, for example, solenoid valves.

Detecting means are provided to detect air flow at least in the conduits 6 and 7. Thus, a detector 14 is provided in conduit 7 and a detector 15 in conduit 6. Each detector 14 and 15 preferably comprises a bobbin 17 which may be biased, for

example, by a spring 16 which bobbin 17 moves in the conduit in response to air movement in that conduit. The movement may be detected desirably electronically, for example, by interruption of a light beam across the conduit or relatively by some other means. As alternatives, the detectors 14 and 15 could comprise thermocouples or thermistors with a sensing circuit or a device to measure increased or decreased pressure relative to atmosphere at some point connected to the mouth piece 3.

The nebulizer 1 may, if required, be provided with a power source 20, for example, electrical or pneumatic or otherwise as required and the power source 20 may be turned on by a control unit 21. A compressed air nebulizer must be turned on and off now and then, although this is not so important when ultrasonic nebulizer is used. This turning on may be, for example, at the start of inhalation through mouth piece 3 or at some time after this and may be turned off on the opening of the valve 8 if desired to enable a rest to be taken at the start of the inhalation signals.

Turning the production of aerosol on and off during breathing could also reduce the dose of drug given per breath and this would allow more breaths to be taken for a given dose and thereby achieve greater precision of doseage.

A counter 22 may be provided to keep a count of the number of breaths taken and this may be pre-settable so that, for example, an alarm sounds or the dispenser stops delivering aerosol after the required number of breaths have been taken. The counter may begin incrementing when the start of the

inhalation is detected.

A power "on" pulse circuit 23 is provided and when the dispenser is turned "on" a signal is forwarded from power "on" pulse circuit 23 and signal circuitry 24 indicates by visual or audio means that a breath should be taken by the user. The valves 9 and 10 are closed and valve 8 is opened. This allows inhalation of aerosol formed by the nebulizer 1 in the reservoir 4 by the drawing of breath through the inlet port 25. The state of breathing is detreated and, for example, when the start of inhalation is detected by the detecting means comprising the flow sensor 14, timer 26 begins and after a present delay the valve 8 is closed. At this time, timer 27 is started and valve 9 is opened about this time and this, together with the non-return valve 12, allows inhalation of air through the inlet 28. After timer 27 has run for its present time, valve 9 is closed and the inhale signals at 24 are turned off. The exhale signals at 35 are then turned on and valve 10 is opened which, together with the non-return valve 13, allows exhalation through the outlet port 29. When the start of exhalation is detected by the flow sensor 15, timer 30 is started and after this has run for its present time, the valve 10 is closed and the exhale signals from generator 35 are turned off. The inhale signals from generator 24 are then turned on and the valve 8 opens to restart the cycle when inhalation occurs.

In the embodiment of Figs. 3 and 4, a compressed air nebulizer is used, which is able to be switched on and off and the intermittent nature of the operation allows selection of the running period to achieve a desired result. A conduit 2 is provided

from the nebulizer 1 to a mouth piece 3 and the conduit 2 may lead from a cloud chamber or aerosol reservoir 4. Thus, particles produced by the nebulizer 1 may pass through the reservoir 4 along the conduit 2 to the mouth piece 3. A branch conduit leads from the conduit 2 which allows air to be exhaled. A conduit 7 extends from the chamber 4. Non-return valves 11 and 13 allow air flow in only the desired direction.

Detecting means are provided to detect air flow at least in the conduits 6 and 7. Thus, a detector 14 is provided in conduit 6 and a detector 15 in conduit 7. Each detector 14 and 15 preferably comprise a bobbin 17 which may be biased, for example, by a spring 16 which bobbin 17 moves in the conduit in response to air movement in that conduit. The movement may be detected desirably electronically, for example, by interruption of a light beam across the conduit or relatively by some other means. As alternatives, the detectors 14 and 15 could comprise thermocouples or thermistors with a sensing circuit or a device to measure an increased or decreased pressure relative to atmosphere at some point connected to the mouth piece 3.

The nebulizer 1 may, if required, be provided with a power source 20, for example, electrical or pneumatic or otherwise as required, and the power source 20 may be turned on by a control unit 21. This turning on may be, for example, at the start of exhalation through mouth piece 3 or at some time after this and may be turned off at some time after this.

Again, a counter 22 may be provided to keep

a count of the number of breaths taken and this may be pre-settable so that, for example, an alarm sounds or the dispenser stops delivering aerosol after the required number of breaths have been taken. The counter may begin incrementing when the start of the inhalation is detected.

A power on pulse circuit is provided and when the dispenser is turned "on" a signal is forwarded from power on pulse circuit 23 and signal circuitry 35 indicates by visual or audio means that a breath should be taken by the user. This allows inhalation of aerosol formed by the nebulizer 1 in the reservoir 4 by the drawing of breath through the inlet port 25. When the start of inhalation is detected by the detecting means comprising the flow sensor 15, timer 30 begins. After 30 has run for its pre-set time the exhale signals at 24 are then turned on, which indicates that the user should exhale and signals at 35 are turned off. When the start of exhalation is detected by the lower sensor 14, timer 26 and timer 27 are started. After timer 27 has run for its present time the aerosol generator is turned on. After timer 26 has run for its pre-set time, the aerosol generator is turned off and signals at 24 are turned off and signals at 35 turned on. When inhalation occurs, the timer 30 is started to repeat cycle.

In use, the nebulizer 1 can be used to generate an aerosol of material such as insulin but which clearly could comprise other materials such as, for example, drugs for use in the treatment of asthmatic conditions. The drug used may dictate whether a compressed air or ultrasonic nebulizer is used.

Thus, it can be seen that at least in the preferred form of the invention, a dispenser and/or a method of dispensing are provided which have the advantage that the drug in aerosol form is released at that stage of the breath cycle where it is most efficaceous and is withheld at other times. In general, this will be at the beginning of the inhalation of the breathing cycle and the invention has been described in relation to such a construction. The provision of signals to which the user matches his breathing also tends to ensure that the breath is held for a sufficient time for the aerosol particles to settle in the lungs. The rate of breathing may also be controlled and, in particular, decreased resulting in deeper breathing and thereby increased deposition of the aerosol particles in the lower lung.

CLAIMS

1. A method of dispensing inhalable material characterised by comprising, in combination, the steps of indicating to a patient that a breath should be taken, detecting the state of breathing and causing or allowing said inhalable material to be supplied to the mouth or nose of the patient during a selected part of the period of inspiration.

2. A method of dispensing inhalable material as claimed in Claim 1, characterised in that said selected part of the period of inspiration is towards the beginning of the period of inspiration.

3. A method of dispensing inhalable material as claimed in either Claim 1 or Claim 2, characterised in that said method further includes the step of indicating to said patient when to exhale.

4. A method of dispensing inhalable material as claimed in any one of the preceding Claims, characterised in that said method further includes the step of indicating to said patient when to inhale.

5. A dispenser comprising a supply means (1) to supply inhalable material in inhalable form, said supply means being in connection with atmosphere and a mouth piece (3) and characterised by further including flow control means (8) to allow or substantially prevent flow between said supply means and said mouth piece and said supply means and said atmosphere, signalling means (24) to indicate to the user when to inhale, detection means (14 and 15) to detect the commencement of inspiration and/or

expiration and to cause said flow control means to cause or allow said inhalable material to move from said supply means to said mouth piece during a selected part of the period of inspiration.

6. A dispenser as claimed in Claim 5, characterised in that said supply means comprises an aerosol generator (1).

7. A dispenser as claimed in Claimed 6, characterised in that said aerosol generator comprises a nebulizer (1).

8. A dispenser as claimed in Claim 6, characterised in that said supply means comprises an aerosol propellant.

9. A dispenser as claimed in any one of the Claims 5 to 8, characterised in that said indicating means further provides an indication to a user of when to exhale.

10. A dispenser as claimed in any one of Claims 5 to 9, characterised in that said control means are provided to control said flow control means, at least some operations of said control means being controlled by said detection means.

11. A dispenser as claimed in any one of Claims 5 to 10, characterised in that conduits (7, 2) are provided between said supply means and an atmosphere and between said supply means and said mouthpiece and wherein a pair of branch conduits (5, 6) are provided one (5) to allow inhalation other than past said supply means and the other said further conduit (6) provided to allow breath to be exhaled.

12. A dispenser as claimed in Claim 6 and any claim dependent thereon, characterised that control means are provided to control said aerosol generator means at least some operations of said control means being initiated by said detection means.

13. A dispenser as claimed in Claim 12, characterised in that a branch conduit (6) is provided to allow breath to be exhaled.

14. A dispenser as claimed in Claim 11, characterised in that preferably non-return valves (11, 12, 13) allow breathing in a single direction only in said conduit and said branch conduits.

15. A dispenser as claimed in any one of Claims 5 to 14, characterised in that said detection means comprise a bobbin (17) moved by the breath of the patient and a light beam positioned so that said bobbin can interrupt said light beam.

16. A dispenser as claimed in any one of Claims 5 to 14, characterised in that said flow control means comprise one or more of a thermocouple or thermistor with a sensing circuit, a device to measure an increase or decrease pressure relative to atmospheric pressure, or a bobbin associated with a movement detector.

17. A dispenser as claimed in any one of Claims 5 to 16, characterised in that said signalling means (24, 35) comprise means to generate audible or visible signals to said user.

FIG 1

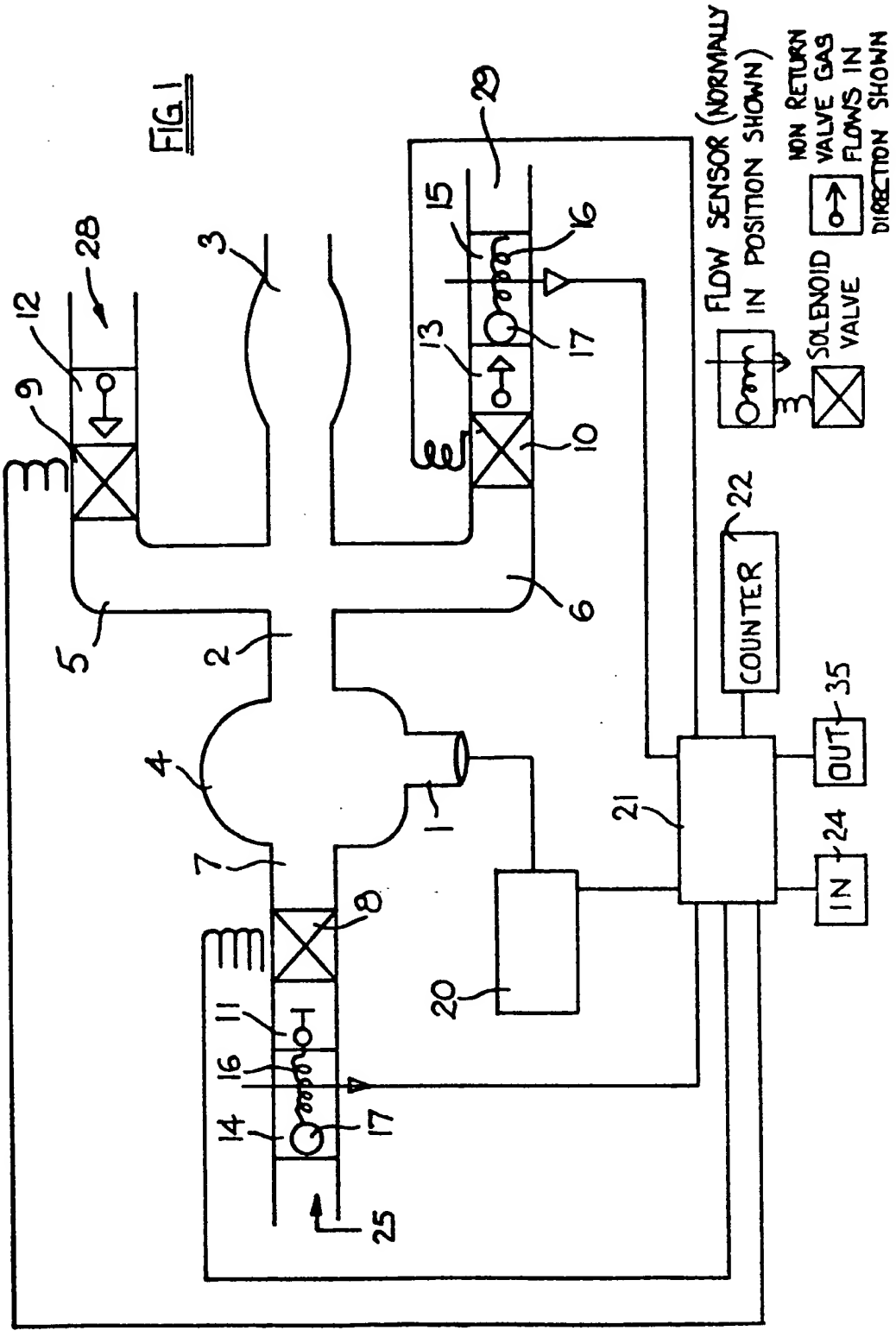

FLOW SENSOR (NORMALLY IN POSITION SHOWN)
NON RETURN VALVE GAS FLOWS IN DIRECTION SHOWN
SOLENOID VALVE
COUNTER
OUT
IN
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
20
21
22
24
25
28
29
35

FIG. 2

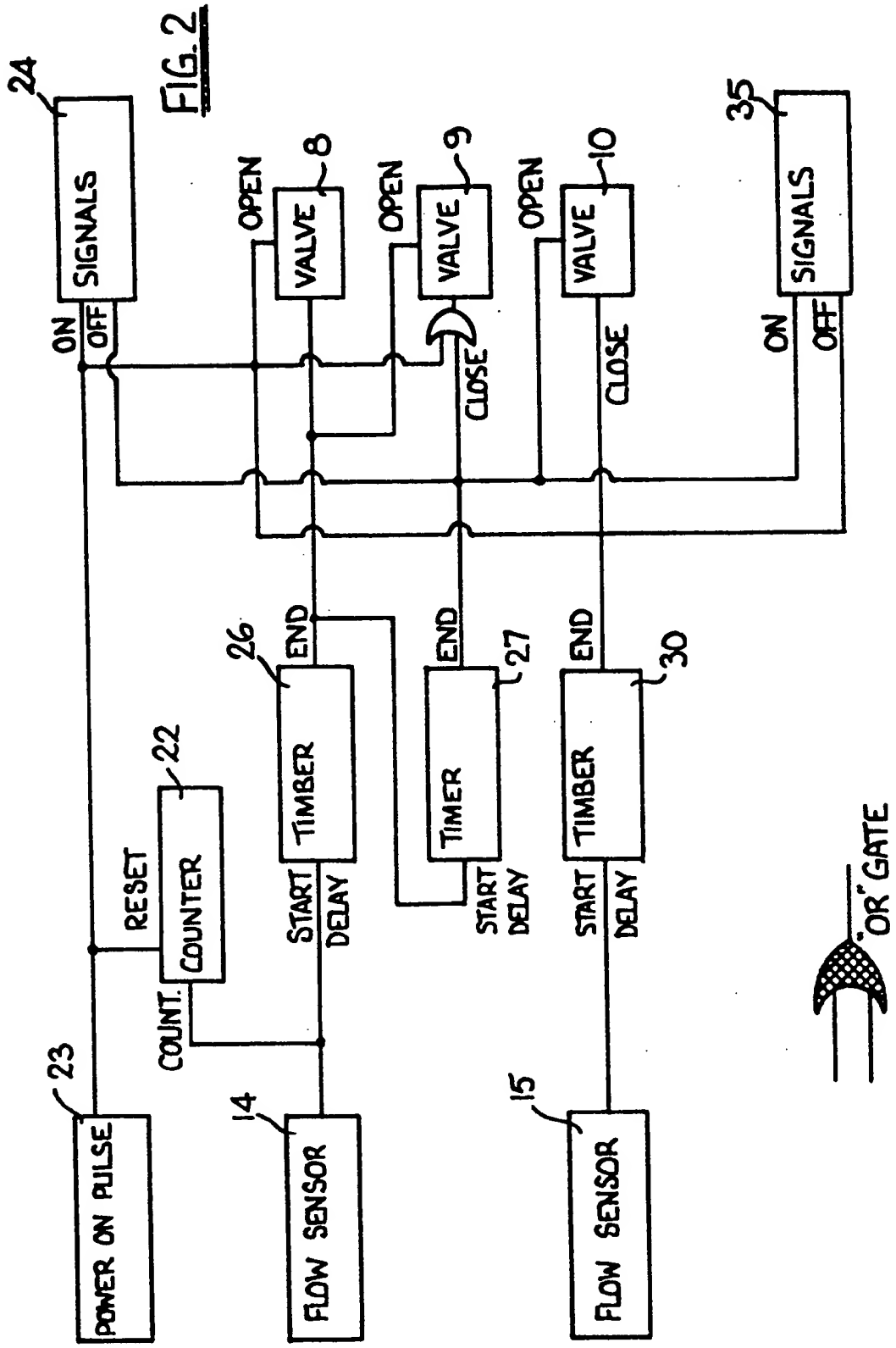

24
SIGNALS
ON
OFF
OPEN
8
VALVE
OPEN
9
VALVE
CLOSE
OPEN
10
VALVE
CLOSE
35
SIGNALS
ON
OFF
26
END
TIMBER
START
DELAY
27
END
TIMER
START
DELAY
30
END
TIMBER
START
DELAY
22
RESET
COUNTER
COUNT.
23
POWER ON PULSE
14
FLOW SENSOR
15
FLOW SENSOR
"OR" GATE

FIG. 3

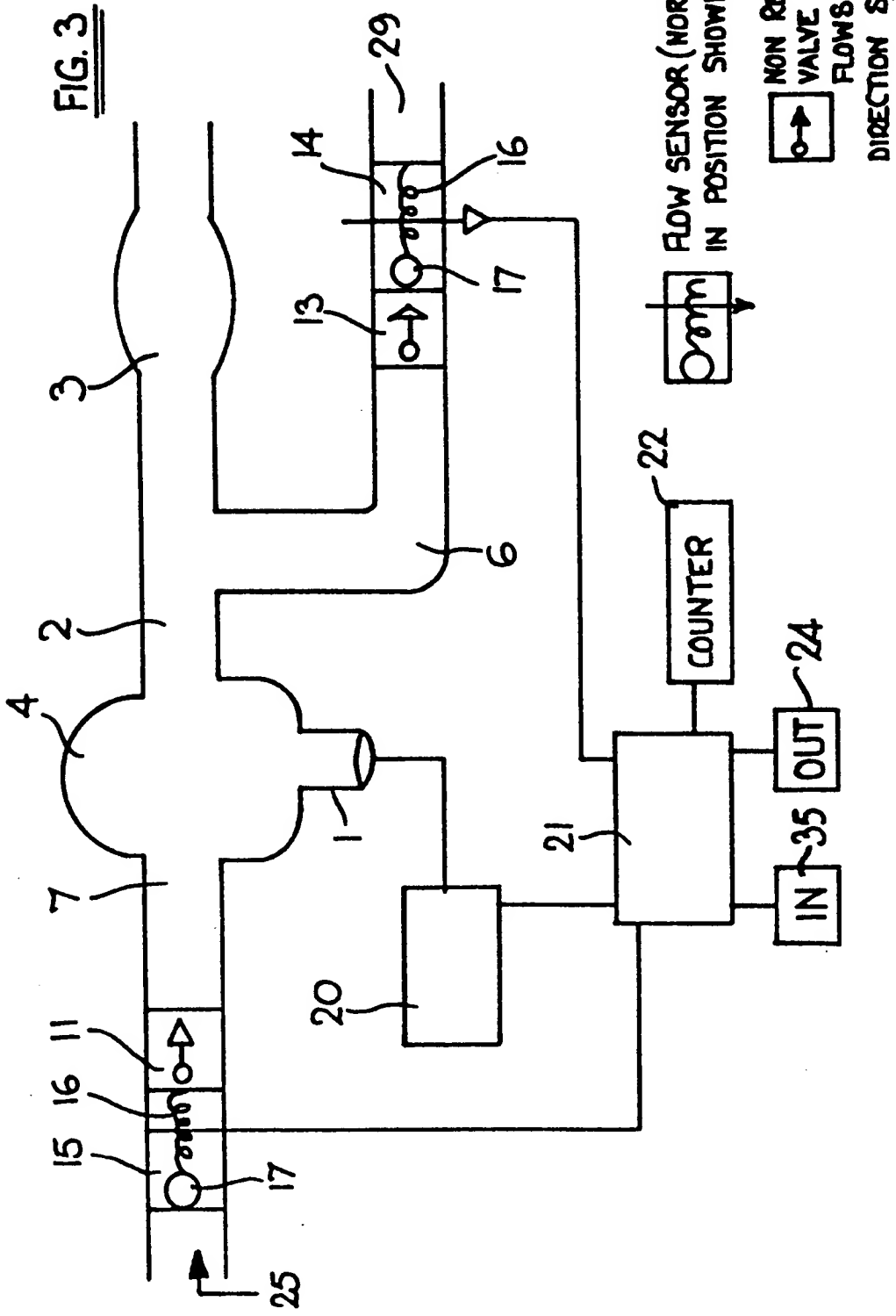
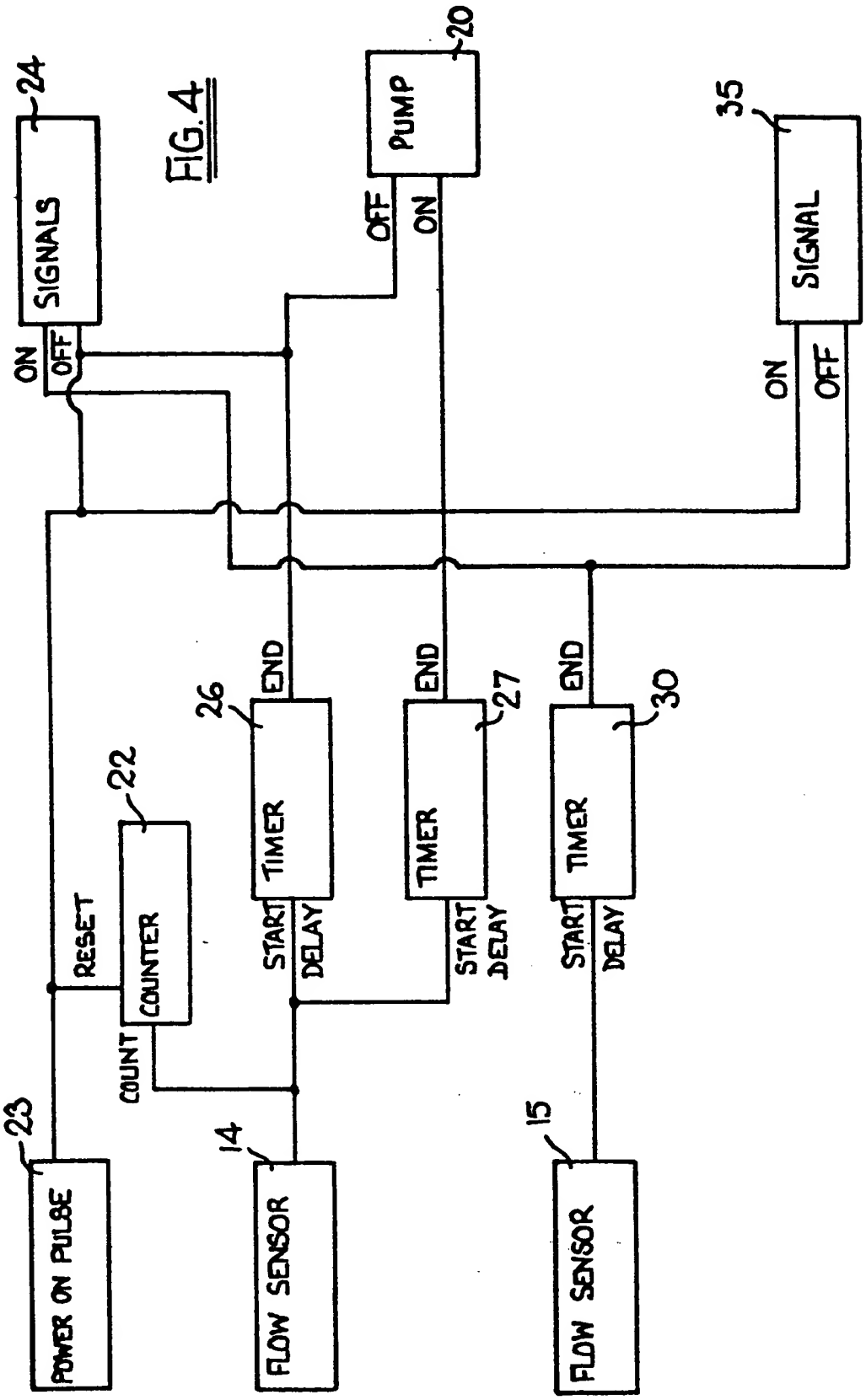

29
14
16
17
13
3
2
4
6
7
1
22
COUNTER
24
OUT
35
IN
21
20
11
16
15
17
25
FLOW SENSOR (NORMALLY IN POSITION SHOWN)
NON RETURN VALVE GAS FLOWS IN DIRECTION SHOWN

FIG. 4


24
SIGNALS
ON
OFF
20
PUMP
OFF
ON
35
SIGNAL
ON
OFF
26
TIMER
END
START
DELAY
27
TIMER
END
START
DELAY
30
TIMER
END
START
DELAY
22
COUNTER
RESET
COUNT
23
POWER ON PULSE
14
FLOW SENSOR
15
FLOW SENSOR